

**REMARKS**

The Final Office Action mailed on January 26, 2009 has been reviewed and the comments of the Examiner carefully considered. Claims 1-20 are pending. Claims 1 and 20 have been amended. Support for these amendments may be found in the specification at, for example, page 5, lines 8-12. No new matter has been added by way of these amendments.

**Drawings Objections**

The Examiner objected to the drawings under 37 CFR 1.83(a). Applicants respectfully submit this objection is improper as no drawings were submitted in the instant application. Applicants respectfully request withdrawal of the drawing objection.

**Rejections under 35 U.S.C. § 102**

Claims 1, 4-5, 13-15, and 18-19 currently stand rejected under 35 U.S.C. § 102(b) as allegedly being anticipated by Webster (US 4,541,426). Applicants respectfully disagree and assert that the claims are not anticipated for the following reasons.

As set forth in MPEP § 2133, a rejection under 35 U.S.C. § 102(b) requires that the claimed invention was patented in this or a foreign country more than one year prior to the date of application for patent in the United States. Anticipation exists only when the cited reference discloses all the elements, features, or limitations. *Carella v. Starlight Archery and Pro Line Co.*, 804 F.2d 135, 138 (Fed. Cir. 1986). Thus, “[t]here must be no difference between the claimed invention and the reference disclosure, as viewed by a person of ordinary skill in the field of the invention.” *Scripps Clinic & Research Foundation v. Genentech, Inc.*, 927 F.2d 1565, 1576 (Fed. Cir. 1991).

Applicants respectfully submit that the Webster patent does not anticipate applicants’ claim 1 because Webster does not teach or describe all of the claim limitations. More specifically, Webster fails to teach the element in applicants’ claim 1 of:

“a first portion which comprises a flexible plasticized hydrophilic polymer matrix having an internal cellular structure, and a second portion which comprises a flexible plasticized hydrophilic polymer matrix having a relatively

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continuous internal structure, wherein the first and second portion are of the ***same material***" (emphasis added).

Applicants have amended claim 1 to further clarify that the second portion includes an outward facing surface that is a skin-contactable surface. In other words, the wound contacting hydrogel layer (*i.e.*, the "second portion") in applicants' invention has a relatively continuous internal structure, while the hydrogel layer distal to the wound (*i.e.*, the "first portion") has an internal cellular structure. These layers are of the ***same material***.

Conversely, the wound contacting layer in Webster does not have a relatively continuous internal structure, but rather is formed from a water swellable polymeric material having an internal cellular structure (*see, e.g.*, col. 2, lines 14-15; col. 2, lines 49-64; col. 5, lines 10-12; col. 9, lines 1-22; **FIGS. 1-3**). Therefore, because Webster does not disclose or suggest a wound contacting layer having a relatively continuous internal structure, the cited reference does not disclose all of the elements of the applicants' claim 1, and the rejection of claim 1 under 35 U.S.C. § 102(b) should be withdrawn.

Further, the layers of Webster are not of the same material as one is formed from a water swellable polymeric material and the other is formed from a non-swellable polymeric material. The layer distal to the wound in Webster is formed from a non-swellable polymeric material (*see, e.g.*, col. 2, lines 17-22; col. 4, lines 34-52; col. 9, lines 1-22; **FIGS. 1-3**). This difference in layer materials is critical to the device of Webster:

"When the first layer of the wound dressing of the present invention is placed in contact with a wet surface, moisture is taken up into the layer and the layer swells and so expands. The second layer being non-swellable or less swellable does not expand as much as the first layer. It has been found that when the two layers are adhered over their surfaces the stress caused by differential swelling is relieved by the second layer deforming and by the apertures opening. When the apertures are opened exudate can more readily pass through the dressing. As the exudation diminishes the first layer becomes drier and tends to return to its unswollen state. The apertures thereby tend to close. The presence of the dressing will keep the surface of the wound moist which is believed to be beneficial to rapid wound healing" (col. 3, lines 28-44).

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Thus, applicants further respectfully submit that the Webster reference cannot be properly modified to suggest the limitations of applicants' because MPEP 2143.01(V) expressly states that a proposed modification of a prior art invention cannot render that invention "unsatisfactory for its intended purpose". If it does, "there is no suggestion or motivation to make the proposed modification". MPEP 2143.01(V). With regard to the rejection of the pending claims, replacing the material of either layer so that both layers are of the same material would disallow the differential swelling that occurs in Webster, thereby rendering that prior art invention unsuitable for its intended purpose.

As Webster does not disclose or suggest a wound dressing wherein the hydrogel layers of the same material, the cited reference does not disclose all of the elements of the applicants' claim 1, and the rejection of claim 1 under 35 U.S.C. § 102(b) should be withdrawn. Further, applicants submit that claims 4-5, 13-15, and 18-19 are thereby allowable as depending from an allowable independent claim.

### **Rejections under 35 U.S.C. § 103**

Claims 2 and 20 currently stand rejected under 35 U.S.C. § 103(a) as allegedly being unpatentable over Webster. Applicants respectfully disagree and assert that the claims are not anticipated for at least the reasons discussed above with respect to claim 1.

Claim 3 currently stand rejected under 35 U.S.C. § 103(a) as allegedly being unpatentable over Webster in view of Takahashi et al. (US 5,972,452). Applicants respectfully traverse this basis for rejection and request reconsideration and withdrawal thereof. Takahashi et al. discloses a sheet shaped oxygen absorbing member according to the present invention comprises a lamination in the order of a separator layer, a base layer having an adhesive layer, an oxygen absorbing layer and a gas permeable layer, the gas permeable layer being directly secured to the base layer at the periphery of the lamination, and is structured to be capable of attaching by readily peeling off from the separator layer. Takahashi et al. does not disclose a wound dressing comprising a wound contacting hydrogel layer having a relatively continuous internal structure, or a hydrogel layer distal to the wound having an internal cellular structure, wherein these layers are of the same material. Thus, as Takahashi et al. cannot cure the deficiencies of Webster, claim 3 is thereby allowable as written as depending from an allowable independent claim.

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Claims 6-12 currently stand rejected under 35 U.S.C. § 103(a) as allegedly being unpatentable over Webster in view of Nielsen (US Published Appln. No. 2003/0153860). Applicants respectfully traverse this basis for rejection and request reconsideration and withdrawal thereof. Nielsen discloses a wound dressing comprising a backing layer, a skin facing layer and an absorbent layer between the backing layer and the skin facing layer, characterised in that at least a part of the absorbent layer is adjacent to the backing layer, the backing layer and the absorbent layer are mutually displaceable, and that the skin facing layer is located at the skin facing surface of the backing layer. Nielsen does not disclose a wound dressing comprising a wound contacting hydrogel layer having a relatively continuous internal structure, or a hydrogel layer distal to the wound having an internal cellular structure, wherein these layers are of the same material. Thus, as Nielsen cannot cure the deficiencies of Webster, claims 6-12 are thereby allowable as written as depending from an allowable independent claim.

Claims 16-17 currently stand rejected under 35 U.S.C. § 103(a) as allegedly being unpatentable over Webster in view of Gilman et al. Applicants respectfully traverse this basis for rejection and request reconsideration and withdrawal thereof. Gilman et al. discloses an adhesive wafer, which is especially suitable for use as a faceplate for an ostomy appliance but may also be used as a wound dressing, has an adhesive layer of hydrocolloid-containing skin barrier material and a flexible backing layer extending over one surface of the adhesive layer. Gilman et al. does not disclose a wound dressing comprising a wound contacting hydrogel layer having a relatively continuous internal structure, or a hydrogel layer distal to the wound having an internal cellular structure, wherein these layers are of the same material. Thus, as Gilman et al. cannot cure the deficiencies of Webster, claims 16-17 are thereby allowable as written as depending from an allowable independent claim.

**Conclusion**

Applicants respectfully submit that the claims are in condition for allowance. An early Notice of Allowance is therefore earnestly solicited. Applicants invite the Examiner to contact the undersigned at (215) 963-5337 to clarify any unresolved issues raised by this response.

The Director is hereby authorized to charge/credit Deposit Account No. **50-0310** (Billing No. 101713-5026) for any other required fees, deficiencies or overpayments in connection with this Response.

Respectfully submitted,

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